

REMARKS

Claims 1-106, 108-110 and 112 are canceled. Claims 107, 111 and 113-119 are now pending for the Examiner's consideration.

Applicant respectfully requests favorable consideration of the pending claims.

1. Claims 110, 112, 118 and 119 were objected to, for the reasons set forth on pages 2-3 of the Office Action. The Examiner notes that claims 110 and 118 are identical in scope, and claims 112 and 119 are identical in scope. By the present amendments, claims 110 and 112 have been canceled. Applicants believe the objection has been overcome and respectfully request that it be withdrawn.

2. Claims 107 and 110-119 were rejected under 35 U.S.C. § 103(a) as being unpatentable over International Application Publication WO 01/37820 to Shenoy et al. ("Shenoy"), for the reasons set forth on pages 3-9 of the Office Action. Applicants respectfully traverse.

Shenoy '820 discloses various ranges for the formulation components. In particular, Shenoy '820 discloses ranges of the active ingredient of 0.01-10%, 0.01-7.5% and 0.01-5% (see, e.g., page 92); and 5-90%, 10-80% and 15-75% (see, e.g., page 96). Shenoy further discloses a particular example having an active ingredient in an amount of 28% (see page 233). Other ranges are described in oil-based formulations (see, e.g., page 98). For the reasons that follow, Applicants respectfully suggest that it would not have been obvious to modify the teachings of Shenoy to select the malate salt of the instantly claimed compound and the specific narrow ranges of components, to make the present invention.

As the Examiner acknowledges on page 3 of the Office Action, Shenoy does not disclose the L-malate salt of 5-(5-fluoro-2-oxo-1,2-dihydro-indol-3-ylidenemethyl)-2,4-dimethyl-1H-pyrrole-3-carboxylic acid (2-diethylamino-ethyl)-amide. In Example 1 of the present application, a formulation is shown using the *free base* compound and in an amount of 65% by weight— an amount outside the scope of the present claims, but within some of the broad ranges taught by Shenoy. As shown in paragraph 0470 of the present application publication (US 2004/0229930), this formulation results in a composition having a bulk density of *only 0.44 kg/L*. Low bulk density is particularly disadvantageous in a solid

formulation, as the composition is difficult to handle and capsules are difficult to fill. Replacing the free base with the L-malate salt but maintaining a high weight percent of the active ingredient (75%; see Comparative Example in paragraphs 0478-0479) results in a composition having undesirable sticking problems in the manufacturing process, again making capsule formation difficult.

In contrast, formulations of the present invention *using the L-malate salt* of 5-(5-fluoro-2-oxo-1,2-dihydro-indol-3-ylidenemethyl)-2,4-dimethyl-1H-pyrrole-3-carboxylic acid (2-diethylamino-ethyl)-amide and in amounts of 40% by weight or 15.2% by weight results in compositions having bulk densities approximately 50% greater (0.64 to 0.67 kg/L; Examples 3 and 4, paragraphs 0472-0475) and displaying no sticking problems (Comparative Example). It would not have been obvious to select from the disclosure of Shenoy the L-malate salt rather than the free base (or another salt) and further to select the weight percentage of the active ingredient in order to produce a composition having improved bulk density and processing characteristics. Further, with respect to claims 114-117, the comparative examples clearly show that the properties of the formulation such as bulk density are not inherent in the Shenoy disclosure.

Thus, Applicant believes the present claims would not have been obvious over the Shenoy disclosure, and respectfully request that the rejection under § 103(a) be reconsidered and withdrawn.

Applicant believes all claims are now in condition for allowance. Should there be any issues that have not been addressed to the Examiners satisfaction, Applicant invites the Examiner to contact the undersigned attorney.

If any fees other than those submitted herewith are due in connection with this response, including the fee for any required extension of time (for which Applicant hereby petitions), please charge such fees to Deposit Account No. 161445.

Respectfully submitted,

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